
OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER

NEW ANIMAL DRUG APPLICATION (NADA) MEMORANDUM RECOMMENDING APPROVAL (MRA)

I. PURPOSE

This Guide describes the format for an NADA MRA that is part of the approval package for a new animal drug application.

II. PROCEDURE TO FOLLOW

The approval package for an application typically contains (among other documents) the following documents as described in CVM Policy and Procedures Guide 1240.3120:

- MRA
- FOI Summary
- Approval Letter
- Draft Regulation
- Labeling (one copy of each piece of labeling)
- Environmental Documents (if any)

Reviewers should provide these documents in **Draft** when forwarding the approval package through administrative review channels.

For original NADA approvals, reviewers should address the MRA **to** the Center Director, **through** the Director, Office of New Animal Drug Evaluation (ONADE). For most supplemental approvals, reviewers should address the MRA **to** the Director, ONADE, **from** the appropriate Division Director. However,

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reviewers should address supplemental approvals that permit a new claim, new species, or change in RX/OTC status the same as for original approvals: **to** the Center Director, **through** the Director, ONADE.

NOTE: *Reviewers should include the following seventeen paragraphs (#1-17) in the MRA. Some sections, however, may not be applicable to all approvals (i.e., paragraphs 2-7, 9-12, and 15). If any of these paragraphs are not applicable, reviewers should indicate, "Not applicable to this submission" under the paragraph heading. For those sections that are applicable, the reviewer should include the language in plain text verbatim, with specific information to address the italics.*

III. FORMAT FOR MRA

Date *<insert date>*

From Director, Division of *<name>* (HFV-xxx)

Subject ***<NADA number and submission information; for example, "Original NADA xxx-xxx, A-0000">*** – **MEMORANDUM RECOMMENDING APPROVAL**

To *<Director Name>*
Director, *<Center for Veterinary Medicine, (HFV-1) or Office of New Animal Drug Evaluation, CVM (HFV-100)>*

If to Center Director,
Through Director, ONADE (HFV-100)_____

Request Under Consideration: *<narrative paragraph describing the current approval request.>* "The sponsor, *<company name,>* has submitted *<type of application>* requesting approval for *<xxxxx.>* The sponsor submitted a current signed Form FDA 356V dated *<insert date>* with this application."

1. General Information:

a. File Number:	*<insert file number e.g., NADA xxx-xxx (INAD xxxx)>*
b. Sponsor:	*<insert company name>* *<insert company address>* Drug Labeler Code: *<insert code number from 21 CFR 510.600>*
c. Established Name:	*<insert drug's established name>*
d. Proprietary Name:	*<insert product's proprietary name>*
e. Dosage Form:	*<insert dosage form>*
f. How Supplied:	*<insert how supplied>*
g. How Dispensed:	*<insert Rx, OTC, or VFD>*
h. Amount of Active Ingredients:	*<insert the amount of active ingredient>*
i. Route of Administration:	*<insert route of administration>*
j. Species/Class:	*<insert species/class>*
k. Recommended Dosage:	*<insert recommended dosage>*
l. Pharmacological Category:	*<insert pharmacological category>*
m. Indications:	*<insert indication(s)>*

2. Target Animal Safety:
Refer to the Freedom of Information (FOI) Summary for more detail. *<Reference dates and submission numbers of submission/review document(s) and technical section complete letter, e.g., See Veterinary Medical Review dated <date,> (INAD xxxx <submission code,> HFV-xxx, <name>), and CVM technical section complete letter (INAD xxxx <submission code>) dated <date>.> <Insert additional animal safety information unique to the application, as appropriate.>*

3. Drug Effectiveness:
Refer to the FOI Summary for more detail. *<Reference dates and submission numbers of submission/review document(s) and technical section complete letter, e.g., See Veterinary Medical Review dated <date,> (INAD xxxx <submission code,>HFV-xxx, <name>), and CVM technical section complete letter (INAD xxxx <submission code>) dated <date>.> <Insert additional drug effectiveness information unique to the application, as appropriate.>*

4. Human Safety:
If drug is intended for use in food species:
Refer to the FOI Summary for more detail. *<Reference dates and submission numbers of submission/review document(s) and technical section complete letter, e.g., See Human Food Safety Review dated <date,> (INAD xxxx <submission code,>HFV-xxx, <name>), and CVM technical section complete letter (INAD xxxx <submission code>) dated <date>.> <Insert any additional human food safety information (including tissue tolerances, ADI, withdrawal times, etc.) as appropriate.> <Address user and environmental safety as appropriate.>*

If drug is intended for use in non-food species:
Data on human food safety, pertaining to drug residues in food, were not required for approval of this NADA. This drug is to be labeled for use in *<insert non-food species,>* which are non-food animals.

5. Freedom of Information (FOI) Summary:
A summary of the safety and effectiveness data, in compliance with 21 CFR 514.11, will be available for public disclosure in the Dockets Management Branch (HFA-305) upon publication of approval of this application in the FEDERAL REGISTER.

6. Labeling:
<Insert statement concerning acceptability of the draft labeling.> <Provide basis for acceptance of draft labeling, e.g., in this MRA or the final Primary Division review of the draft labeling and associated letter to sponsor, as applicable.> The approved labeling submitted by the sponsor on *<insert date>* is attached to the FOI summary.

7. Chemistry, Manufacturing Methods, and Controls:
<Insert appropriate paragraph for this application. For originals, site dates of reviews and technical section complete letter; for supplemental applications, state whether there is a change from the original application. For example, "There are no changes submitted for the Chemistry, Manufacturing Methods, and Controls.">

Expiry dating: *<not required for supplements if there are no CMC changes.>*

GMP compliance: *<insert as appropriate:* According to the GMP status check dated <date,> HFV-140 has ascertained that the sponsor is in compliance with cGMP (current Good Manufacturing Practice) regulations. *Or, if there are no supplemental CMC changes,* Because there are no Chemistry, Manufacturing Methods, and Control changes, GMP compliance verification is not required.>

8. Environmental Assessment:
<Insert statement concerning environmental assessment, categorical exclusion, etc., as appropriate. Include dates and submission numbers of consulting reviews or concurrence by HFV-145, if applicable.>

9. Special Concurrence:
<Insert whether the agency requires special concurrence for this approval. Ordinarily there are none. If there are grounds for special concurrence, provide details here.>

10. Bioresearch Monitoring Status:
Bioresearch Monitoring records in HFV-234 were examined and do not provide an adequate basis for refusal to approve this application. *<Reference HFV-234 memo, as appropriate, e.g., See HFV-234 memo, dated <date>.>*

11. Drug Experience Report (DER) Status:
The Primary Reviewer examined adverse drug experience/events records on <*insert date*> and determined that they do not provide an adequate basis for refusal to approve this application.

12. Supplemental Applications:
<Insert basis for determination of category I or II supplemental application (21CFR514.106), or N/A for original application.>

13. Patent Term:
<Insert the patent number and expiration date for each patent that the sponsor has submitted with this application; or, "No patents submitted with this application.">

14. Exclusivity:
Note whether exclusivity was granted or not. If the new animal drug qualifies for exclusivity, include the citation for the section of the Federal Food, Drug, and Cosmetic Act (the Act) that provides for exclusivity (512(c)(2)(F)(i), 512(c)(2)(F)(ii), 512(c)(2)(F)(iii), or 512(c)(2)(F)(v)) and note the duration.

For examples of appropriate exclusivity language, see Guide 1243.5780.

15. Regulation:
The draft regulation (FRDTS #CVMxxxxx) is attached to amend the animal drug regulations <*insert CFR paragraph number(s) being amended*> to reflect the approval of a <*insert type of application*> new animal drug application providing for safe and effective use of <*insert drug name*> in <*insert species, etc., as appropriate.*>

16. Communications Staff Notification:
Has the Division sent advance notification of this pending approval to HFV-12 following the appropriate criteria in CVM Policy and Procedures Guide 1240.2325?

☐ Yes ☐ No

17. Recommendation:

We recommend that the approval letter be signed and sent to the sponsor. *<Also include the following sentence, if applicable:>* We also recommend that the FEDERAL REGISTER document providing for approval of this New Animal Drug Application be signed and forwarded for publication in the FEDERAL REGISTER.

_____ _____

<insert Division Director's > signature block>

<insert Team Leader's signature block>

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<insert Reviewer's signature block>

IV. DISTRIBUTION COPIES

cc: HFV-199, NADA Orig.
HFV-102, Green Book

<Author's name, HFV-#, date>

The preparer should include name, date, and HFV code for each reviewing official in the draft review process. Example provided below:

Draft-Reviewing Official: *<insert initials and date>*
HFV-###, Team Leader's name
HFV-###, Division Director's name
HFV-###, Quality Assurance Team Official's name